

Message Text

UNCLASSIFIED

PAGE 01 STATE 045315
ORIGIN HEW-06

INFO OCT-01 NEA-10 ISO-00 OES-06 /023 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/PHS/OASH/OIH: REVANS
NEA/EGY:KHONAN(INFO)
OES/APT/BMP:ACHAPMAN(INFO)
NE/ME/E:BPORTER(INFO)

-----020134 102710 /63

P 012318Z MAR 77
FM SECSTATE WASHDC
TO AMEMBASSY CAIRO PRIORITY

UNCLAS STATE 045315

E.O. 11652: N/A

TAGS: TBIO, EG

SUBJECT: FDA REGULATIONS ON TOOTHPASTE CONTAINING
ANTIBIOTICS

REF: CAIRO 2463

PASS SCIENTIFIC ATTACHE

1. FDA ADVISES THAT IT HAS CHECKED REFERENCE(S) TO NOTICE
APPEARING IN THE LITERATURE CITED REGARDING TOOTHPASTE CON-
TAINING PENICILLIN OR OTHER ANTIBIOTICS. SUCH REFERENCES
HAVE NO MEANING WHAT-SO-EVER CONCERNING THE APPROVAL OF A
"NEW DRUG" PRODUCT AS REQUIRED BY THE FEDERAL FOOD, DRUG
AND COSMETIC ACT, AS AMENDED.

2. ANY TOOTHPASTE CONTAINING PENICILLIN OR OTHER ANTI-
BIOTICS WOULD BE REGARDED AS A "NEW DRUG" UNDER SECTION 201
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(P) OF THE F D AND C ACT AND COULD NOT, REPEAT NOT BE
MARKETED IN THE U.S. WITHOUT AN APPROVED NDA (NEW DRUG AP-
PLICATION). IN ADDITION, THE ANTIBIOTICS WOULD REQUIRE
CERTIFICATION UNDER SECTION 507 OF THE ACT.

3. THERE ARE NO REPEAT NO TOOTHPASTES CONTAINING PENI-
CILLIN OR ANY OTHER ANTIBIOTIC WHICH HAVE BEEN APPROVED

FOR MARKETING IN THE U.S. THROUGH NDA PROCEDURES AT THIS TIME.

4. COPY OF F, D, AND C ACT AND SET OF CURRENT CODE OF FEDERAL REGULATIONS (CFR'S) BEING AIRMAILED TO EMBASSY. NEW CFR VOLUMES WILL BE REVISED AS OF 1 APRIL 1977, HOWEVER, COPIES WILL NOT BE AVAILABLE UNTIL SOMETIME IN JUNE 1977. PRICE OF NEW SET NOT AVAILABLE AT THIS DATE.

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Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: FOOD & DRUG REGULATIONS
Control Number: n/a
Copy: SINGLE
Sent Date: 01-Mar-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE045315
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770070-1168
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t197703104/aaaadnsx.tel
Line Count: 72
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 875d88ac-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
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Review Withdrawn Fields: n/a
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Status: NATIVE
Subject: FDA REGULATIONS ON TOOTHPASTE CONTAINING ANTIBIOTICS
TAGS: TBIO, EG, US
To: CAIRO
Type: TE
vdkgvwkey: odhc://SAS/SAS.dbo.SAS_Docs/875d88ac-c288-dd11-92da-001cc4696bcc
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